PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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397-7602

13 MAR 2005

PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	09.06.2004
Applicant's or agent's file reference ES/13310.4	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA 03/01429	19.09.2003	20.09.2002

International Patent Classification (IPC) or both national classification and IPC
C12Q1/00, C12Q1/00

Applicant
MEDINNOV, INC. et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☐	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 20.01.2005

Name and mailing address of the international preliminary examining authority:

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I. Basis of the opinion

1. With regard to the ~~elements~~ of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-29 as originally filed

Claims, Numbers

1-45 as originally filed

Drawings, Sheets

1/21-21/21 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   - ☐ the description, pages:
   - ☐ the claims, Nos.:
   - ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-3,9,10, 23-25,27-29,35,36
Inventive step (IS)	Claims	1-45
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 The following documents (D1-D3) are referred to in this communication; the numbering will be adhered to in the rest of the procedure:

D1: PLEGGE ET AL: 'Analysis of ternary mixtures with a single dynamic microbial sensor and chemometrics using a nonlinear multivariate calibration', ANAL CHEM, 01. June 2000, vol. 72, no. 13, pages 2937 to 2942,

D2: LIDEN ET AL: 'Rapid alcohol determination in plasma and urine by column liquid chromatography with biosensor detection', J PHARM AND BIOMED ANAL, 01. September 1,

D3: US 5312590 A 1994.05.17 998, vol. 17, no. 6-7, pages 1111 to 1128.

2 NOVELTY

2.1 The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of claim 1-3,9,10,23-25,27-29,35,36, is not new in the sense of Article 33(2) PCT.

2.1.1 D3 discloses (the references in parentheses applying to this document): a device for measuring multiple analytes simultaneously comprising a support base (figure 3); a mixed electrode system comprising a platinum working electrode, a platinum auxiliary electrode, and a silver reference electrode (column 4, lines 22-25,64-69; claim 11); an enzymatic reaction means (glucose oxidase: column 7, lines 9-24); a detector (figure 9); a data processor capable of converting amplified signals into numerical data representing the concentration of two analytes; a layer of a TTF/Nafion on which glucose oxidase is bound (column 7, lines 9-24); a protective polycarbonate membranae (column 7, lines 9-24), and a reagent well (figure 3). Ferrocene mediators are also disclosed (column 2, lines 25-27). The subject-matter of claims 1-3,9,10,27-29,35,36 is therefore not new (Article 33(2) PCT).

2.1.2 D1 discloses (the references in parentheses applying to this document): a method for simultaneously measuring the concentration of acetate, L-lactate and succinate involving a) reacting a plurality of reference samples having known concentrations and proportions of said related analytes (p. 2939, column 1, paragraph 2), b) establishing a kinetic profile having at least two points for each of said plurality of reference samples (p. 2940), c) reacting a test sample and determining concentrations of related components (table 2). The method involves multiple regression analysis and reaction kinetic equations (p. 2941, column 1, paragraph 3). The subject-matter of claims 23-25 is therefore not new (Article 33(2) PCT).

3 INVENTIVE STEP

3.1 The present application does not meet the requirements of Article 33(1) PCT, because the subject-matter of claims 4-8,11-22,26,30-34,37-45 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1.1 The subject-matter of claims 4-8,11-22 merely adds routine modification options to the subject-matter of claim 1 and is therefore obvious to a person skilled in the art. For this reason the subject-matter of claims 4-8,11-22 does not involve an inventive step in the sense of Article 33(3) PCT.

3.1.2 The subject-matter of claims 30-34,37-45 merely adds routine modification options to the subject-matter of claim 27 and is therefore obvious to a person skilled in the art. For this reason the subject-matter of claims 30-34,37-45, does not involve an inventive step in the sense of Article 33(3) PCT.

3.1.3 The subject-matter of claim 26 is not considered inventive under Article 33(3) PCT.

3.1.3.1 Here, D2 is considered the closest prior art. This document discloses (the references in parentheses applying to this document): an enzyme electrode for detection of ethanol and methanol in biological fluids following separation by liquid chromatography (abstract).

3.1.3.2 The additional technical feature of claim 26 over D2 is that the method uses

kinetic models to obtain methanol and ethanol concentrations simultaneously from the electrical signal obtained from the biological fluid.

3.1.3.3 The technical effect associated with this modification is that no time-consuming liquid chromatography step is required to separate the methanol and ethanol.

3.1.3.4 The problem to be solved by the present invention may therefore be regarded as the provision of a faster assay for measuring ethanol and methanol in biological fluids.

3.1.3.5 The solution to this problem is to use kinetic models to obtain methanol and ethanol concentrations simultaneously from the electrical signal obtained from the biological fluid.

3.1.3.6 The solution represents the analogous use of a known technique, which is described in D1 (ref. 3.1.2). D1 describes this technique in relation to determining the concentrations of acetate, L-lactate and succinate, simultaneously. Like methanol and ethanol, these are related substrates for the same enzyme pathway. Thus, it would be obvious to arrive at the solution proposed in claim 26 by combining the teachings of D2 and D1. Therefore, the subject-matter of claim 26 does not involve an inventive step in the sense of Article 33(3) PCT.

4 INDUSTRIAL APPLICABILITY

4.1 The subject-matter of claims 1-45 is industrially applicable in the field enzyme electrodes (Article 33(4) PCT).